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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,728	12/05/2003	George F. Kick	ONSET.002A	1724

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EXAMINER

SIMPSON, SARAH A

ART UNIT	PAPER NUMBER
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3731

NOTIFICATION DATE	DELIVERY MODE
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10/29/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/728,728	Applicant(s) KICK ET AL.	
	Examiner SARAH A. SIMPSON	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25,27,28,47,49,50,60,62,63,72,74,75 and 83-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25,27,28,47,49,50,60,62,63,72,74,75 and 83-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/21/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/21/2010 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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4. **Claims 25, 27-28, 60, 62-63 and 83-89** rejected under 35 U.S.C. 103(a) as obvious over **Nishtala et al. (US 2001/0012950 A1)** in view of **Trudell et al. (US 5,158,545)** and further in view of **Fourkas et al. (US 6,808,520 B1)**.

Regarding claims 25, 27-28, 60, 62-63 and 83-89, Nishtala discloses a method of providing percutaneous access, said method comprising: making an incision through skin; inserting a guidewire through the incision in the skin and into or through the renal collection system, percutaneously inserting an elongate tubular structure through the incision in the skin and over the guidewire and into the renal collection system, the elongate tubular structure comprising a distal region, a proximal region, and a tapered region all of which may be folded ([0096]; figs. 1B-D). Nishtala teaches various tubular embodiments that may be expanded by any active or passive dilating elements such as by inflating a balloon ([0081], [0086], [0098]) that is positioned within an interior lumen of said elongate tubular structure to expand and unfold said distal region of said elongate tubular structure radially around its longitudinal axis from said first, smaller cross-sectional profile to said second, greater cross-sectional profile. Nishtala also teaches the balloon may be removed from said distal region of said elongate tubular structure to open the interior lumen in said elongate tubular structure, the interior lumen open to an external environment outside the skin on its proximal end and open to the renal collection system on its distal end ([0173]).

Nishtala fails to disclose wherein the tapered region of the tubular structure is between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile and longitudinal creases, the proximal region having a

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second, greater cross-sectional profile, and releasing the elongate tubular structure from a constraining tubular jacket, the constraining tubular jacket sharing the same longitudinal axis as the elongate tubular structure, wherein releasing the elongate tubular structure from the constraining tubular jacket comprises tearing said tubular jacket along a perforation. However, Nishtala teaches that all of the dilating elements may be used with a membrane or protective oversheath ([0082]).

However, Trudell teaches a method of providing percutaneous access, said method comprising: an elongate tubular structure (12) having a first, folded, substantially continuous, smaller cross-sectional profile (fig. 2); expanding said elongate tubular structure radially around its longitudinal axis from said first, smaller cross-sectional profile to a second, greater cross-sectional profile (figs. 4, 5); and inflating a balloon (50) that is positioned within an interior lumen of the folded distal region of the elongate tubular structure to radially expand said elongate tubular structure from said first, smaller cross-sectional profile to said second, greater cross-sectional profile (column 6, lines 66-68); and releasing the elongate tubular structure from a constraining tubular jacket (18), the constraining tubular jacket sharing the same longitudinal axis as the elongate tubular structure, wherein releasing the elongate tubular structure from the constraining tubular jacket comprises tearing said tubular jacket along a perforation (28) and separating the jacket from the elongate tubular structure (column 6, lines 53-65).

Forukas teaches a circumferentially continuous tapered tubular dilator and sheath wherein the tapered region of the tubular structure is between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional

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profile and the proximal region having a second, greater cross-sectional profile (figs. 22, 23).

Given the teachings of Trudell and Forukas, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Nistala wherein the tapered region of the tubular structure is between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile and the proximal region having a second, greater cross-sectional profile; and releasing the elongate tubular structure from a constraining tubular jacket, the constraining tubular jacket sharing the same longitudinal axis as the elongate tubular structure, wherein releasing the elongate tubular structure from the constraining tubular jacket comprises tearing said tubular jacket along a perforation. Nishtala teaches that all of the dilating elements may be used with a membrane or protective oversheath ([0082]). The tapered region of the folded tubular member provides for a safer, faster, and easier placement of the tube as well reducing trauma by allowing the narrow initial penetration of the tube to be expanded to a size capable of receiving other surgical instruments, as disclosed by Forukas. The constraining tubular jacket provides advantageous delivery methods, as the jacket prevents the tube from premature expansion.

5. **Claims 47, 49-50, 72 and 74-75** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Nishtala et al. (US 2001/0012950 A1)** in view of **Trudell et al. (US 5,158,545)** and **Forukas et al. (US 6,808,520 B1)** and further in view of **Bonutti et al. (5,961,499)**.

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Regarding claims 47, 49-50, 72 and 74-75, Nishtala discloses a method of providing percutaneous access, said method comprising: making an incision through skin; inserting a guidewire through the incision in the skin and into or through the renal collection system, percutaneously inserting an elongate tubular structure through the incision in the skin and over the guidewire and into the renal collection system, the elongate tubular structure comprising a distal region, a proximal region, and a tapered region all of which may be folded ([0096]; figs. 1B-D). Nishtala teaches various tubular embodiments that may be expanded by any active or passive dilating elements such as by inflating a balloon ([0081], [0086], [0098]) that is positioned within an interior lumen of said elongate tubular structure to expand and unfold said distal region of said elongate tubular structure radially around its longitudinal axis from said first, smaller cross-sectional profile to said second, greater cross-sectional profile. Nishtala also teaches the balloon may be removed from said distal region of said elongate tubular structure to open the interior lumen in said elongate tubular structure, the interior lumen open to an external environment outside the skin on its proximal end and open to the renal collection system on its distal end ([0173]).

Nishtala fails to disclose wherein the tapered region of the tubular structure is between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile and the proximal region having a second, greater cross-sectional profile, and releasing the elongate tubular structure from a constraining tubular jacket, the constraining tubular jacket sharing the same longitudinal axis as the elongate tubular structure, wherein releasing the elongate tubular structure from the constraining

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tubular jacket comprises tearing said tubular jacket along a perforation. However, Nishtala teaches that all of the dilating elements may be used with a membrane or protective oversheath ([0082]).

However, Trudell teaches a method of providing percutaneous access, said method comprising: an elongate tubular structure (12) having a first, folded, substantially continuous, smaller cross-sectional profile (fig. 2); expanding said elongate tubular structure radially around its longitudinal axis from said first, smaller cross-sectional profile to a second, greater cross-sectional profile (figs. 4, 5); and inflating a balloon (50) that is positioned within an interior lumen of the folded distal region of the elongate tubular structure to radially expand said elongate tubular structure from said first, smaller cross-sectional profile to said second, greater cross-sectional profile (column 6, lines 66-68); and releasing the elongate tubular structure from a constraining tubular jacket (18), the constraining tubular jacket sharing the same longitudinal axis as the elongate tubular structure, wherein releasing the elongate tubular structure from the constraining tubular jacket comprises tearing said tubular jacket along a perforation (28) and separating the jacket from the elongate tubular structure (column 6, lines 53-65).

Forukas teaches a circumferentially continuous tapered tubular dilator and sheath wherein the tapered region of the tubular structure is between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile and the proximal region having a second, greater cross-sectional profile (figs. 22, 23).

Given the teachings of Trudell and Forukas, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Nistala wherein the tapered region of the tubular structure is between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile and the proximal region having a second, greater cross-sectional profile; and releasing the elongate tubular structure from a constraining tubular jacket, the constraining tubular jacket sharing the same longitudinal axis as the elongate tubular structure, wherein releasing the elongate tubular structure from the constraining tubular jacket comprises tearing said tubular jacket along a perforation. However, Nishtala teaches that all of the dilating elements may be used with a membrane or protective oversheath ([0082]). The tapered region of the folded tubular member provides for a safer, faster, and easier placement of the tube as well reducing trauma by allowing the narrow initial penetration of the tube to be expanded to a size capable of receiving other surgical instruments, as disclosed by Forukas. The constraining tubular jacket provides advantageous delivery methods, as the jacket prevents the tube from premature expansion.

Nistala fails to disclose wherein the elongate tubular body has a beveled distal tip.

However, Bonutti et al. teach an expandable elongate tubular body (400) which as a beveled distal tip (fig. 21) comprising a leading edge and a trailing edge.

Given the teachings of Bonutti et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Fourkas et al.

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with a beveled distal tip. The beveled distal tip would provide a smooth and efficient introduction of the expandable sheath into the body.

Response to Arguments

Applicant's arguments with respect to claims 25, 27, 28, 47, 49, 50, 60, 62, 63, 72, 74, 75 and 83-89 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH A. SIMPSON whose telephone number is 571-270-3865. The examiner can normally be reached on Monday - Friday 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sarah A Simpson/
Examiner, Art Unit 3731
10/24/2010

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
10/25/10